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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,595	02/23/2007	Christopher Speirs	SPEI3003/ESS	3605
23364 7590 11/10/2010 BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314-1176				
EXAMINER YU, HONG				
ART UNIT 1613		PAPER NUMBER		
MAIL DATE 11/10/2010		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/581,595

**Applicant(s)**

SPEIRS ET AL.

**Examiner**

HONG YU

**Art Unit**

1613

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-11, 14, 18, 20, 24-26, 28-30, 32, 33 and 40-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 7-11, 14, 18, 20, 24-26, 28-30, 32, 33 and 40-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/16/2010 has been entered.

### ***Status of claims***

The amendment filed on 09/16/2010 is acknowledged. Claims 1-6, 12, 13, 15-17, 19, 21-23, 27, 31, and 34-39 have been canceled. Claims 7-11, 14, 18, 20, 24-26, 28-30, 32, 33, and 40-46 are under examination in the instant office action.

Applicant's amendments and arguments filed 09/16/2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdraw. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application. Applicant has argued both 35 USC 103(a) rejections together and the Examiner will respond accordingly at the end of this action under "Response to Arguments".

**New ground of rejections**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claims 7-10, 14, 18, 20, 24, 26, 28-30, 32, 40-42, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Speirs (US 5,834,021).***

Speirs meets all of the limitations of claims 7, 40, 45, and 46. Speirs discloses a preparation of pellets comprising: a) mixing water with component composition to form a paste; b) extruding the formed paste to form extrudate; c) spheronizing the extrudate; d) drying the sphere pellets (column 5, line 1-8) with the diameter of the particles are in the range of 1000 to 1400  $\mu\text{m}$  (example 1; reproduced below) which is interpreted as 100% of the particles being in the range of 1000 to 1400  $\mu\text{m}$ .

#### EXAMPLE I

5 wt % PRED-MSB was dry mixed with 40 wt % microcrystalline cellulose (Avicel™ PH 101), 50 wt % lactose and 5 wt % croscarmellose sodium (Ac-Di-Sol™). Water was added and the mixture mixed for 10 minutes to form an extrudable paste. The paste was extruded from a 25 mm diameter bowl through a 1 mm diameter tube of about 5 mm length at a rate of about 100 mm/min and spheronised on an 8 in (20 cm) plate rotated at about 1000 rpm for 10 to 15 min to provide pellets having a diameter in the range 1000–1400  $\mu$ m. The resultant pellets were dried at 50° C. for 30 min on a fluidised bed.

The rate of release of PRED-MSB from the pellets at pH 1.2 and pH 6.4 was measured and the results are shown in FIG. 6.

Although Speirs is silent about the amount of water in the composition, the amount of the water determines the size distribution of the particles produced according to the disclosure in the instant specification (page 4 line 22 through page 5, line 18) with the process disclosed by Speirs being the same as the claimed process and the range of the size distribution of the particles produced by the process disclosed by Speirs within the range of the size distribution of the particles produced by the claimed process, the amount of the water used in the process disclosed by Speirs must be within the range of the amount of water used in the claimed process. The composition taught by Speirs must inherently have the same amount of water because all of their particles made with the same components fall within the instantly claimed size range and therefore 100% of the particles, which is about 98%, are in that particle size distribution of from about 800 to about 1500 microns. Thus, the composition taught by

Speirs inherently have the same amount of water as instantly claimed otherwise the particle size range would be different.

Speirs meets all of the limitations of claims 8-10, 14, 18, 20, 24, 26, 28-30, 32, 41, and 42. Speirs discloses the composition consisting essentially of (column 4, line 61-65) 5 to 20% by weight of prednisolone (column 4, line 58-60), 10 to 30% by weight of croscarmellose sodium (column 4, line 48-57 and example 10), 40% by weight of microcrystalline cellulose (example 1), and 50% by weight of lactose (example 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claims 11, 33, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speirs (US 5,834,021), as applied to 7-10, 14, 18, 20, 24, 26, 28-30, 32, 40-42, 45, and 46, and further in view of Mulye (US 2004/0224017 A1 with effective filing date of 03/14/2003).***

***Applicant's claims***

Applicants claim the said component composition of step a) consisting essentially of metronidazole, a rheology modifying agent, a sugar, and a cellulose (see claims 11 and 33).

Claims 43 and 44 recite the said component composition of step a) consisting essentially of paracetamol, a rheology modifying agent, a sugar, and a cellulose.

***Determination of the Scope and Content of the Prior Art***

***(MPEP 2141.01)***

The teachings of Speirs are discussed above and applied in the same manner.

***Ascertainment of the Difference between Scope of the Prior Art and the Claims***

***MPEP 2141.02)***

Speirs does not teach the active agent being metronidazole and paracetamol.

This deficiency is cured by Mulye who teaches prednisolone, metronidazole, and paracetamol are equivalent active agents in a preparation comprising mixing, extruding, spheronizing, and drying (paragraph 39 and example 9).

***Finding of Prima Facie Obviousness Rational and Motivation***

***(MPEP 2142-2143)***

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Speirs and Mulye to substitute prednisolone with metronidazole or paracetamol as an active agent in the composition disclosed by Speirs. Prednisolone, metronidazole, and paracetamol being equivalent active agents in a preparation comprising mixing, extruding, spheronizing, and drying was well known to a person of ordinary skill in the art at the time of the invention. The motivation for substituting prednisolone with metronidazole or paracetamol as an active agent flows from prednisolone, metronidazole, and paracetamol having been used as equivalent active agents in a preparation comprising mixing, extruding, spheronizing, and drying in the prior art. As shown by the recited teachings, instant claims are no more than substituting prednisolone with its equivalent such as metronidazole or paracetamol. It therefore follows that the instant claims define prima facie obvious subject matter.

***Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Speirs (US 5,834,021), and further in view of Wolozin (US 6,472,421 B1)***

Applicants claim the said sugar being lactose monohydrate (see claim 25).

***Determination of the Scope and Content of the Prior Art***

***(MPEP 2141.01)***

The teachings of Speirs are discussed above and applied in the same manner.

***Ascertainment of the Difference between Scope of the Prior Art and the Claims***

***MPEP 2141.02)***

Speirs does not teach the said sugar being lactose monohydrate.

This deficiency is cured by Wolozin who teaches that lactose can be lactose monohydrate and lactose anhydrous (column 9, line 40 and 41).

***Finding of Prima Facie Obviousness Rational and Motivation***  
***(MPEP 2142-2143)***

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Speirs and Wolozin to specify lactose monohydrate as the lactose in the composition disclosed by Speirs. Monohydrate and lactose anhydrous were well known as two types of lactose in pharmaceutical compositions to a person of ordinary skill in the art at the time of the invention. The motivation for specifying lactose being monohydrate lactose flows from monohydrate lactose having been one of the two types of lactose and having being used in the composition taught by Wolozin. As shown by the recited teachings, instant claims are no more than specifying a conventional type of lactose. It therefore follows that the instant claims define prima facie obvious subject matter.

***Response to Arguments***

Applicant's arguments, filed on 09/16/2010, have been fully considered but they are moot in view of new ground of rejections. However the examiner would like to address the following arguments:

Applicant argues that none of the prior art indicates that the amount of water used in such a process has any impact at all on particle size distribution let alone the level of fine control observed by the inventors.

Respectfully, the Examiner cannot agree for the following reasons. First of all Spiers performs the same method resulting with particles the size of which is within the instantly claimed amounts. Clearly the same amount of water must be used in order to achieve such uniform size distribution and therefore this concept has already been practiced in the art by Spiers. Although Spiers may not realize the effect of water has on the size distribution, the composition taught by Speirs inherently have the same amount of water as instantly claimed and meet the recited limitation of the claim.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on M-F 8:50 am-5:20 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian-Yong Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./  
Examiner, Art Unit 1613

/Ernst V Arnold/  
Primary Examiner, Art Unit 1613